REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 6, 14, 16, 20, and 24-36 are withdrawn from consideration because they are drawn to non-elected subject matter. This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier. Upon entry of this amendment, claims 1-5, 7-13, 15-19, and 21-23 are pending in this application. Claims 1-4, 7-8, and 21-23 are currently amended. Claims 37-39 are new.

Support for the amendments is provided in the specification. As indicated by the examiner, support for the recitation "recombinant" peptide in amended claim 1 is found at, for example, page 24, lines 24-32 of the specification. Support for the recitation "chemically synthesized" in amended claim 1 is found, for example, at page 4, lines 15-17 of the specification. Support for the recitation of "SEQ ID No. 1 or a fragment thereof, wherein said fragment comprises at least SEQ ID No. 2 or at least the fragment encoded by nucleotides 763 to 855 of Figure 4" in amended claim 1 is found throughout the specification and, for example, in Figure 4 and Example 5.

Support for amended claim 2 is found in, for example, original claim 8, the sequence listing, and throughout the specification.

Support for amended claim 4 is found at, for example, page 3, line 37 to page 4, line 4 and original claim 4.

Support for amended claim 7 is found, for example, in original claim 6.

Support for newly added claim 37 is found, for example, in Figure 4 and Example 5.

Support for newly added claim 38 is found throughout the specification and, for example, at page 3, lines 24-31 and page 6, lines 16-27, and page 9, lines 11-16.

Support for newly added claim 39 is found, for example, in Figure 4 and Example 5.

The amendments to claims 3 and 21-23 are made merely to conform to U.S. claim language and formalities, and to provide consistent language throughout the claims.

Objections

The examiner objects to the specification as including an embedded hyperlink and/or other browser-executable code, citing pages 3 and 5 of the specification. Applicants thank the examiner for his suggestion to delete <> and http:// to obviate this rejection. However, pages 3 and 5 of the specification include neither the symbols "< >" nor "http://". Therefore, applicants are confused and request clarification of how to amend the specification.

The examiner further objects to the specification because the recitation "VISTVVANL" in Figure 5 does not include a sequence identifier With this Amendment Applicants submit a substitute sequence listing which includes SEQ ID NO: 9 (VISTVVANL). Applicants also have amended the specification revising the Figure 5 legend to refer to SEQ ID NO: 9 .

Claims 7 and 8 are objected to as depending from non-elected claims. Claim 7 has been amended to independent format, thus obviating this rejection.

Rejection of Claims 1-3, 5, and 7-8 under 35 U.S.C. § 101

Claims 1-3, 5, 7 and 8 are rejected under 35 U.S.C. § 101 as not sufficiently distinguished over peptides as they exist naturally. Applicants would like to thank the examiner for the suggested claim amendments. Further to the examiner's suggestion, independent claims 1 and 7 are amended to recite "recombinant or chemically synthesized" peptides, thus obviating this rejection. As noted by the examiner at page 5 of the Office Action, the recitation "recombinant" finds support in Example 5 at page 24, lines 25-32 of the present specification. The recitation "chemically synthesized" finds support at page 4, lines 15-17.

Applicants respectfully request withdrawal of the rejection of claims 1-3, 5, 7 and 8 under 35 U.S.C. § 101.

Claim Rejections under 35 U.S.C. § 112

Rejection of claims 4 and 5 under 35 U.S.C. § 112, second paragraph

Claim 4 is rejected under the second paragraph of section 112, as allegedly rendered indefinite by inclusion of the term "preferably." Independent claim 4 is amended to delete this term.

Claims 4-5 are rejected as incomplete for omitting a correlation step describing how the results of the assay relate back to the preamble of the method. In its present form, amended claim 4 and dependent claim 5 avoid this rejection.

Applicants respectfully request withdrawal of the rejection of claims 4-5 under 35 U.S.C. § 112, second paragraph.

Rejection of claims 1-3 and 7-8 under 35 U.S.C. § 112, first paragraph

Claims 1-3, and 7-8 are rejected under section 112, first paragraph, as allegedly failing to provide enablement of the claimed peptide compounds. Specifically, the examiner asserts:

> One cannot extrapolate the teachings of the specification to the scope of the claims because the claims are broadly drawn to any and all peptide fragments of 8 consecutive amino acids in length (or peptides comprising a sequence of approximately 9 to 10 amino acids of SEQ ID NO:1 which has at least one mutation or on modification) with or without the biological properties of what is claimed, and applicant has not enabled all of these types of modified peptides because it would not be expected nor could one predict that these modified peptides would be capable of functioning as that which is being disclosed.

Office Action at page 7 (emphasis added).

The present form of the amended claims obviates this rejection. Amended claim 1 recites a "recombinant or chemically synthesized peptide compound, comprising SEQ ID NO: 1 or a fragment thereof, wherein the fragment comprises SEQ ID NO: 2 or a peptide encoded by nucleotides 763 to 855 of Figure 4, and wherein the peptide causes a specific T response." Amended claim 7 recites a peptide compound obtained "by determining a peptide fragment which possesses a sequence of approximately 9 to 10 amino acids comprising an anchoring motif for a given HLA molecule, wherein the peptide fragment comprises SEQ ID NO: 2 or a peptide encoded by nucleotides 763 to 855," "introducing a point modification or mutation at residue 4, 5, 6, 7 or 8," and "determining the immunogenicity of the peptide fragments" by carrying out an Elispot assay.

In their present form, the amended claims avoid this rejection. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejections.

Rejection of claims 4-5, 17 and 20-23 under 35 U.S.C. § 112, first paragraph

Claims 4-5, 17 and 21-23 are rejected under the first paragraph of Section 112. The examiner asserts that

> [t]he claims are not enabled because the specification fails to provide reasonable guidance and objective evidence that one of skill in the art would know how to use the method in any predictable manner or to use the obtained peptides in any

> predictable manner, or to use the pharmaceutical compositions in any predictable manner."

Office Action at page 9. Further, the examiner asserts that "the specification fails to provide reasonable guidance that random synthesis of an infinite number of such peptides through trial and error would provide one of ordinary skill in the art a reasonable expectation of success that such peptides would be immunogenic." Office Action at page 10. The present form of the claims avoids this rejection.

Amended claim 4 recites:

> A method for identifying peptide compounds comprising a sequence which has at least 80% identity with a sequence of approximately 9 to 10 consecutive amino acids of SEQ ID NO: 1, wherein the peptide comprises SEQ ID NO: 2 or a peptide encoded by nucleotides 763 to 855 of Figure 4, comprising:
>
> a) determining a peptide fragment comprising a sequence of approximately 9 to 10 amino acids comprising an anchoring motif for a given HLA molecule,
>
> b) determining the immunogenicity of the peptide fragment obtained in step a)~~,~~ by carrying out an Elispot assay, and
>
> c) identifying the peptide fragment, wherein the peptide fragment is reactive in the Elispot assay, wherein the peptide fragment comprises a sequence which has at least 80% identity with a sequence of approximately 9 to 10 consecutive amino acids SEQ ID NO: 1, and wherein the fragment comprises SEQ ID NO: 2 or a peptide encoded by nucleotides 763 to 855 of Figure 4.

Claims 17 and 21-23 depend from claim 1, which is amended to recite a "recombinant or chemically synthesized peptide compound, comprising SEQ ID NO: 1 or a fragment thereof, wherein the fragment comprises SEQ ID NO: 2 or a peptide encoded by nucleotides 763 to 855 of Figure 4, and wherein the peptide causes a specific T response."

Section 112 mandates that patent applications describe the "manner and process of making and using" the invention. The courts have considered applications to be in compliance with § 112 where the person of skill in the art can practice the invention without

compliance with § 112 where the person of skill in the art can practice the invention without undue experimentation. *See In re Wands, 858* F.2d 731 (Fed. Cir. 1988); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986).

The test for compliance with §112 is not whether experimentation is necessary, but whether any experimentation would be undue in view of what type and amount of experimentation are usual in the field. *See In re Wands*, 858 F.2d at 736-37 ("Enablement is not precluded by the necessity for some experimentation such as routine screening."). *See also* MPEP § 2164.01. The courts have recognized that absolute predictability is not a requirement for §112. Therefore, the amended claims are enabled.

Accordingly, Applicants respectfully request reconsideration and withdrawal of these rejections.

Rejection of claims 1-5, 7-8, 17, and 21-23 under 35 U.S.C. § 112, first paragraph

Claims 1-5, 7-8, 17, and 21-23 are rejected under 35 U.S.C. § 112, first paragraph as failing to provide sufficient written description. The present form of the claims avoids this rejection.

The examiner asserts that "the claims are drawn to a genus of peptide compounds. However, the written description in this case only sets forth a recombinant peptide comprising SEQ ID NO:1 and a recombinant peptide consisting of SEQ ID NO:2 and therefore the written description is not commensurate in scope with the claims which read on an infinite number of variant peptides." Office Action at page 12.

The written description requirement ensures that the skilled artisan would understand, based on the specification, that the inventor possessed the claimed invention at the time the application was filed. *Vas-Cath v. Marhurkar*, 935 F.2d 1555, 1564 (Fed. Cir. 1991). Literal correspondence between the claims and the specification is not required. See In re Wertheim, 541 F.2d 257, 265 (CCPA 1976). Furthermore, breadth alone is not sufficient basis for rejecting claims under the written description requirement. See Fed. Reg. 66(4):1106-1107 (2001). Accordingly, Applicants request withdrawal of this rejection.

Amended claims 1 and 4 are directed to a peptide compound (claim 1) or method of identifying a peptide compound (claim 4) comprising a peptide fragment of SEQ ID NO: 1 wherein the fragment comprises SEQ ID NO: 2 or a peptide encoded by nucleotides 763 to 855 of Figure 4. Similarly, amended claim 7 is directed to a peptide compound obtained "by determining a fragment which possesses a sequence of approximately 9 to 10 amino acids comprising an anchoring motif for a given HLA molecule, wherein the peptide fragment comprises SEQ ID NO: 2 or a peptide encoded by nucleotides 763 to 855," and introducing a point modification or mutation at residue 4, 5, 6, 7 or 8. Accordingly, amended claims 1, 4, and 7, and claim 5, 8, 17, and 21-23, which depend from them, are not directed to "an infinite number of variant peptides." Thus, in their present form, the full scope of the claims is amply supported.

Applicants respectfully request reconsideration and withdrawal of the rejection.

Rejection of claims 7-8 under 35 U.S.C. § 102(b)

Claims 7-8 are rejected under 35 U.S.C. § 102(b) as anticipated by Kato *et al.* (PIR Database, Accession No. JQ0137). Specifically, the examiner asserts that "Kato *et al.* teach a peptide compound that possess 9 to 10 amino acids of SEQ ID NO:1 including at least one mutation or modification with respect to SEQ ID NO:1. Kato *et al.* further teach that said peptide includes that amino acids (SPR-WP) which are derived from SEQ ID NO:2." Office Action at page 15. The present form of the claims obviates this rejection.

An anticipation rejection is only proper where each claim limitation is contained in a single prior art reference. See *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986).

The amended claims recite a peptide or peptide fragment which comprises SEQ ID NO: 2 or a peptide encoded by nucleotides 763 to 855 of Figure 4. The evidence of record does not establish that Kato *et al.* teaches any peptide that includes SEQ ID NO: 2, namely a peptide having the amino acid sequence SPRWWPTCL.

Conclusion

Accordingly, Applicants respectfully request withdrawal of this rejection.

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date Jan 26, 2004

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